Qualification Plan

IQ/OQ/PQ Protocol Pack · Template 02 of 09

Plan No. _____ **Version** _____

Equipment / area name _____ **Equipment ID / asset No.** _____

Location (building, room) _____ **Department** _____

Manufacturer _____ **Model** _____

Serial No. _____ **URS ref.** _____

Equipment type ☐ Stability chamber ☐ Cold room ☐ Refrigerator ☐ Freezer ☐ Ultra-low freezer ☐ Warehouse ☐ Other: _____

1 Approval and change history

This qualification plan must be approved before any part of it is executed. The approval date must be earlier than the date on the first executed data sheet.

Prepared by	Reviewed by	Approved by (QA)
Name _____	Name _____	Name _____
Designation _____	Designation _____	Designation _____
Signature _____	Signature _____	Signature _____
Date _____	Date _____	Date _____

Change history

Version	Date	Description of change	Author

2 Scope

List every item covered by this plan. Qualify each critical item from DQ to PQ.

#	Equipment / area	ID	Type	URS No.	Stages required

3 Qualification sequence

Each stage must be completed, and its deviations closed, before the next one starts.

Stage	Document No.	Planned date	Actual date	Previous stage deviations closed?	Initials
URS				☐ Yes ☐ NA	
DQ				☐ Yes ☐ NA	
FAT (optional)				☐ Yes ☐ NA	
SAT (optional)				☐ Yes ☐ NA	
IQ				☐ Yes ☐ NA	
OQ				☐ Yes ☐ NA	
PQ				☐ Yes ☐ NA	
Release for routine use				☐ Yes ☐ NA	
Periodic review				☐ Yes ☐ NA	

4 Responsibilities

Activity	Engineering	Vendor	Validation	QA	Operations	Name(s)
Write URS	☐	☐	☐	☐	☐	
DQ review	☐	☐	☐	☐	☐	
Execute IQ	☐	☐	☐	☐	☐	
Execute OQ	☐	☐	☐	☐	☐	
Execute PQ	☐	☐	☐	☐	☐	

Activity	Engineering	Vendor	Validation	QA	Operations	Name(s)
Review results (independent)	☐	☐	☐	☐	☐	
Approve protocols and reports	☐	☐	☐	☐	☐	
Release for routine use	☐	☐	☐	☐	☐	

5 Approach

Combined protocols ☐ None ☐ IOQ (IQ + OQ) ☐ OQ + PQ

Justification for combining (if any) _____

Use of vendor / FAT / SAT documents ☐ No ☐ Yes, reviewed and approved by QA

Qualification loggers (model, quantity, calibration certificate Nos.) _____

Seasonal studies planned (dates) _____

6 Requalification policy

Periodic review / requalification interval _____

Justification for the interval (risk, history, monitoring) _____

Event-based triggers: relocation; replacement of controller, compressor, evaporator or control sensor; firmware or software change; new setpoint or range; change in load pattern, racking or layout; recurring excursions or alarm trends; major repair, panel or door replacement.

7 Deliverables

Document	Document No.	Filed?
URS		☐
DQ report		☐
IQ, OQ, PQ protocols (approved)		☐
Executed data sheets and raw logger files		☐
Deviation reports		☐
Calibration certificates		☐
Traceability matrix		☐

Document	Document No.	Filed?
IQ, OQ, PQ reports		☐
Release for routine use		☐